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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL
For FY 2006

[X] Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 225.00

Complete if Known	
Application Number	09/852,966-Conf. #5588
Filing Date	May 10, 2001
First Named Inventor	Rima KADDURAH-DAOUK
Examiner Name	V. Y. Kim
Art Unit	1618
Attorney Docket No.	AVZ-020CNRCE

METHOD OF PAYMENT (check all that apply)

[ ] Check [ ] Credit Card [ ] Money Order [ ] None [ ] Other (please identify): _____

[X] Deposit Account Deposit Account Number: 12-0080 Deposit Account Name: Lahive & Cockfield, LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

[X] Charge fee(s) indicated below
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[X] Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17
[X] Credit any overpayments

FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
Application Type	**Fee ($)**	**Small Entity Fee ($)**	**Fee ($)**	**Small Entity Fee ($)**	**Fee ($)**	**Small Entity Fee ($)**	**Fees Paid ($)**
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	**Fee ($)**	**Small Entity Fee ($)**
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims		**Extra Claims**	**Fee ($)**	**Fee Paid ($)**
_____	- =	_____	x _____	= _____

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims		**Extra Claims**	**Fee ($)**	**Fee Paid ($)**
_____	- =	_____	x _____	= _____

HP = highest number of independent claims paid for, if greater than 3.

Multiple Dependent Claims	
Fee ($)	**Fee Paid ($)**
_____	_____
_____	_____

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets		**Extra Sheets**		**Number of each additional 50 or fraction thereof**	**Fee ($)**	**Fee Paid ($)**
_____	- 100 =	_____	/50	_____ (round **up** to a whole number) x	_____	= _____

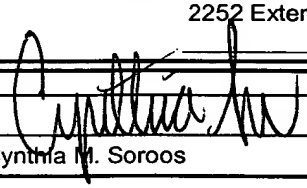
4. OTHER FEE(S) **Fees Paid ($)**

Non-English Specification, $130 fee (no small entity discount)

Other (e.g., late filing surcharge):

2252 Extension for response within second month 225.00

SUBMITTED BY

Signature		Registration No. (Attorney/Agent)	53,623	Telephone	(617) 227-7400
Name (Print/Type)	Cynthia M. Soroos			Date	January 22, 2007

Express Mail Label No. EV 956 470 543 US Dated: January 22, 2007

TRANSMITTAL OF APPEAL BRIEF	Docket No. AVZ-020CNRCE

In re Application of: Rima KADDURAH-DAOUK

Application No.	Filing Date	Examiner	Group Art Unit
09/852,966-Conf. #5588	May 10, 2001	V. Y. Kim	1618

Invention: USE OF CREATINE OR CREATINE COMPOUNDS FOR SKIN PRESERVATION

TO THE COMMISSIONER OF PATENTS:

Transmitted herewith is the Appeal Brief in this application, with respect to the Notice of Appeal filed: April 7, 2006 .

The fee for filing this Appeal Brief is * .

[ ] Large Entity [X] Small Entity

[X] A petition for extension of time is also enclosed.

The fee for the extension of time is $ 225.00 .

[ ] A check in the amount of _____ is enclosed.

[X] Charge the amount of the fee to Deposit Account No. 12-0080 .
This sheet is submitted in duplicate.

[ ] Payment by credit card. Form PTO-2038 is attached.

[X] The Director is hereby authorized to charge any additional fees that may be required or credit any overpayment to Deposit Account No. 12-0080 .
This sheet is submitted in duplicate.

* Appeal Brief Fee was paid on November 7, 2006

Dated: January 22, 2007

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Express Mail Label No. EV 956 470 543 US Dated: January 22, 2007

Express Mail Label No. EV 956 470 543 US Dated: January 22, 2007

Docket No.: AVZ-020CNRCE
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Rima Kaddurah-Daouk

Application No.: 09/852,966 Confirmation No.: 5588

Filed: May 10, 2001 Art Unit: 1618

For: USE OF CREATINE OR CREATINE COMPOUNDS FOR SKIN PRESERVATION Examiner: V. Y. Kim

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDED APPEAL BRIEF

Dear Sir:

As indicated in the Notice of Appeal filed on April 7, 2006, and responsive to the Notification of Non-Compliant Appeal Brief mailed from the U.S. Patent and Trademark Office on November 21, 2006, Appellant hereby appeals the final decision of the Examiner in the above-identified application rejecting the subject matter of the pending claims. For the reasons set forth in this brief, Appellant respectfully requests the Board of Patent Appeals and Interferences to reverse the Examiner's final rejection of the claimed subject matter.

As required under § 41.37(a), this amended brief is filed more than two months after the Notice of Appeal filed in this case, and is in furtherance of said Notice of Appeal.

The fees required under § 41.20(b)(2) were dealt with in the Transmittal of Appeal Brief, originally filed with the U.S. Patent and Trademark Office on November 7, 2006. Accordingly, no additional fee is believed due with this brief.

This brief contains items under the following headings as required by 37 C.F.R. § 41.37 and M.P.E.P. § 1206:

I.	Real Party In Interest
II.	Related Appeals and Interferences
III.	Status of Claims
IV.	Status of Amendments
V.	Summary of Claimed Subject Matter
VI.	Grounds of Rejection to be Reviewed on Appeal
VII.	Arguments
VIII.	Claims
IX.	Evidence
X.	Related Proceedings
Appendix A	Claims
Appendices B-G	Evidence

I. REAL PARTY IN INTEREST

The real party in interest for this appeal is Avicena Group, Inc.

II. RELATED APPEALS, INTERFERENCES, AND JUDICIAL PROCEEDINGS

There are no other appeals, interferences, or judicial proceedings known to Appellant, Appellant's legal representative or the assignee which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

A. Total Number of Claims in Application

There are 17 claims pending in application.

B. Current Status of Claims

1. Claims canceled: 1-67, 71, 74, 86 and 87
2. Claims withdrawn from consideration but not canceled: none
3. Claims pending: 68-70, 72, 73, 75-85 and 88
4. Claims allowed: none
5. Claims rejected: 68-70, 72, 73, 75-85, and 88

C. Claim on Appeal

The claims on appeal are claims 68-70, 72, 73, 75-85, and 88.

IV. STATUS OF AMENDMENTS

An Amendment and Response to Office Action was filed on June 27, 2003 in response to the Office Action dated June 4, 2003 and was entered.

An Amendment and Response to Final Office Action Pursuant to 37 C.F.R. §1.116 and a Notice of Appeal was filed on May 17, 2004 in response to the final office action dated November 26, 2003. The response was not entered.

A Request for Continued Examination Pursuant to 37 C.F.R. §1.114 was filed on August 16, 2004.

An Amendment and Response to Office Action was filed on July 11, 2005 in response to the office action dated January 1, 2005 and was entered.

Appellant did not file an Amendment and Response Pursuant to 37 C.F.R §1.116 in response to the final office action dated October 7, 2005. A Notice of Appeal was filed on April 7, 2006.

V. SUMMARY OF CLAIMED SUBJECT MATTER

One aspect of the invention, as claimed in independent claim 68, provides a method of increasing energy reserves in the skin of a subject suffering from a skin disorder associated with free radicals, aging, sun radiation, stress or fatigue, by administering to the subject an effective amount of creatine or a salt thereof (see, *e.g.*, page 4, lines 18-20).

Another aspect of the invention, as claimed in independent claim 69, provides a method for sustaining energy production in the skin of a subject suffering from a skin disorder associated with free radicals, aging, sun radiation, stress or fatigue, by administering to the subject an effective amount of creatine or a salt of thereof (see, *e.g.*, page 20, lines 9-12, and page 22, lines 6-8).

A further aspect of the invention, as claimed in independent claim 70, provides a method for modulating energy flow in the skin of a subject suffering from a skin disorder associated with free radicals, aging, sun radiation, stress or fatigue, by administering to the subject an effective amount of creatine or a salt thereof (see, *e.g.*, page 20, lines 19-22).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellant presents the following issues for review:

1. Whether claims 68-70, 75-80, 84 and 85 are properly rejected under 35 U.S.C. §103(a) as obvious over Yu *et al.* (U.S. Patent No. 5,702,688; Appendix B) in view of Kaddurah-Daouk *et al.* (U.S. Patent No. 5,324,731; Appendix C) and Kaddurah-Daouk *et al.* (International Application Publication No. WO 96/14063; Appendix D).

2. Whether claims 68-70, 75-85 and 88 are properly rejected under 35 U.S.C. §103(a) as being unpatentable over Le Fur *et al.* (U.S. Patent No. 5,256,649; Appendix E) in view of Carniglia (U.S. Patent No. 4,871,718; Appendix F) and Kaddurah-Daouk *et al.*(International Application Publication No. WO 96/14063; Appendix D) or Kaddurah-Daouk *et al.* (U.S. Patent No. 5,321,030; Appendix G).

VII. ARGUMENTS

A. Rejection of Claims 68-70, 75-80, 84 and 85 Under 35 U.S.C. §103(a)

The Examiner rejects claims 68-70, 75-80, 84 and 85 as obvious over Yu *et al.* (U.S. Patent No. 5,702,688, hereinafter "the '688 patent;" Appendix B) in view of Kaddurah-Daouk *et al.* (U.S. Patent No. 5,324,731, hereinafter "the '731 patent;" Appendix C) and Kaddurah-Daouk *et al.* (International Application Publication No. WO 96/14063, hereinafter "the '063 application;" Appendix D).

The present claims are directed to methods for increasing energy reserves in the (claim 68), sustaining energy production in the skin of a subject (claim 69) or modulating energy flow in the skin of a subject (claim 70) in the skin of a subject suffering from a skin disorder by administering to a subject creatine or a salt thereof, such that energy reserves are increased, the energy production is sustained or the energy flow in modulated in the skin. Claims 75, which depends on any one of claims 68-70 is directed

to the co-administration an effective amount of a skin preserving agent. Claim 76, which depends from claim 75, is drawn to a skin preserving agent that is an antioxidant. Claim 77, which depends from claim 76 is directed to the antioxidants vitamin E and CoQ_{10}. Claim 78, which depends from claim 76, is directed to a skin preserving agent that is an energy-enhancing agent. Claim 79, which depends from claim 78, is drawn to the energy-enhancing agents ATP, nicotinamide and pyruvate. Claim 80, which depends on claim 75, is directed to a skin preserving agent that is a vitamin or a vitamin precursor. Claim 84, which depends on any one of claims 68-70, is directed to the co-administration of a pharmaceutical carrier suitable for topical administration. Claim 85, which depends from any one of claims 68-70, is directed to a subject that is a human.

The Examiner asserts that when the '688 patent, the '731 patent and the '063 patent "are combined together, the underlying mechanism (*i.e.*, modulating skin cell energy using creatine compounds) is clearly present in the treating of skin aging and wrinkle[s] by administering a creatine compound." The Examiner further asserts that

> [i]t is noted that creatine is also found in skin cells as well as brain, heart and muscle cells that is conventionally known knowledge at the time the invention was made...It is readily apparent to any skilled artisan that the energy level modulation by creatine supplement is not limited to the brain, muscle or heart cells but any cells that are associated with creatine kinase/creatine phosphate energy system. Thus, one would have been motivated to use a creatine compound to modify intercellular energy...in the skin cell to treat the diseases associated with imbalanced creatine kinase level.

Specifically, the Examiner is of the opinion that the primary reference, the '688 patent, teaches a treatment of abnormal skin conditions using an amphoteric compound. The Examiner acknowledges that Appellant's claims differ from the '688 patent "in that the claims require increasing energy reserve, sustaining energy production and modulating energy flow in the skin."

The '688 patent teaches compositions for and methods of treating skin disorders using an amphoteric composition comprising an amphoteric compound and at least one of an alpha hydroxyacid or an alpha ketoacid. While the '688 patent discloses that creatine is an example of an amphoteric compound, the '688 patent emphasizes that the active compounds are the alpha hydroxyacids and the alpha ketoacids, not the amphoteric

compounds. The amphoteric compounds are merely included in the amphoteric composition to modulate the pH of the composition and to control the release of the "active ingredients" (*e.g.*, alpha ketoacids and alpha hydroxy acids). Therefore, the '688 patent ***fails to teach or suggest that an amphoteric compound (e.g., creatine) would be useful in any other capacity other than to balance the pH and enhance the ability of the alpha ketoacids and the alpha hydroxyacids to penetrate the skin.***

The Examiner takes the position that the '731 patent teaches "a creatine (or its salts) and its use in the treatment of metastasis of epithelial cells via modifying energy level" and that the '731 patent further "teaches energy balance using creatine kinase in the treatment of other diseases such as psoriasis, wound healing, neurological disorders and cerebrovascular diseases."

The '731 patent also fails to provide any teaching or suggestion which would have led one of ordinary skill in the art to the claimed invention. Specifically, the '731 patent describes methods of inhibiting growth, transformation and/or metastasis of mammalian cells, where the activity of at least one purine metabolic enzyme (*e.g.*, creatine kinase) is elevated, by administering a drug that directly or indirectly reduces the velocity of the enzymatic activity. The '731 patent further describes that reducing the activity of creatine biosynthetic enzymes affects the velocity of the reaction of creatine kinase ***by limiting substrates of creatine kinase (e.g., creatine)*** (see, column 19, lines 37-42). Moreover, the '731 patent teaches the design and use of drugs that are structural analogs of creatine, where the ***analogs differ from creatine*** by "substitution, chain extension and/or cyclization," such that the analogs exhibit "greater specificity for the enzyme, enhanced stability, enhanced uptake into cells, tighter binding to the enzyme or ***better inhibitory activity*** (see, column 20, lines 45-52 and column 21, lines 40-42)." And although the '731 patent suggests that the disruption of cellular energy balance may be important in diseases or disorders, such as psoriasis, arthritis and wound healing, where levels of creatine kinase B are elevated, the '731 patent teaches ***away*** from using creatine or a salt thereof for the treatment of these disorders because ***creatine is a substrate for creatine kinase.*** Thus, the administration of creatine or a salt thereof would be expected to increase the velocity of the reaction of creatine kinase.

In contrast, Appellant's claim methods for increasing energy reserves, sustaining energy production and modulating energy flow in the skin by administering to a subject an effective amount of ***creatine or a salt thereof.*** Accordingly, based on the teaching of the '731 patent, the subject matter presently claimed by Appellant would not have been obvious to one of ordinary skill in the art. Indeed, the '731 patent fails to provide any motivation at all to administer creatine or a salt thereof to a subject suffering from a skin disorder associated with free-radicals, aging, sun radiation, stress or fatigue.

With regard to the '063 application, the Examiner asserts that the '063 application

> teaches a treatment of disesase (*e.g.*, neurological diseases) which are caused by abnormalities in an energy state, wherein the induction or inhibition of creatine kinase is a cause or a consequence of disease and modulating its activity would modulate energy flow and affect cell function

and that the '063 application

> specifically teaches that creatine (or its salts) is used for modifying energy of cells in stress via increasing energy reserve, sustaining energy production and modulating energy flow.

The '063 application, alone or in combination with the '731 patent, fails to overcome the deficiencies of the primary reference. The '063 application teaches methods of treating diseases of the nervous system (*e.g.*, Alzheimer's disease, Parkinson's disease, Huntington's disease and the like) in a subject by administering to the subject an amount of one or more compounds (*e.g.*, creatine, phosphocreatine or analogs thereof) which modulate one or more of the structural or functional components of the creatine kinase/phosphocreatine system (*e.g.*, creatine, creatine phosphate, creatine kinase and transporter of creatine) sufficient to prevent, reduce or ameliorate the symptoms of the disease. Further, the '063 application discloses ***cyclocreatine***, not creatine or a salt thereof, "modifies the flow of energy of cells in stress (see, page 40, lines 6-8)." Moreover, although the '063 application discloses that the function of the ***creatine kinase/phosphocreatine system*** includes the regeneration of energy in cells and that modulation the activity of creatine kinase would modulate energy flow and affect cell function, there is no teaching or suggestion of methods for increasing energy reserves, sustaining energy production and ***modulating energy flow in the skin*** by

administering to a subject an ***effective amount of creatine or a salt thereof*** to a subject suffering from a skin disorder associated with free-radicals, aging, sun radiation, stress or fatigue. Accordingly, based on the teaching of the '063 application, alone or in combination with the '688 patent or the '731 patent, the subject matter presently claimed by Appellant would not have been obvious to one of ordinary skill in the art.

In sum, none of the cited references, either alone or in combination, provide any teaching or suggestion which would have motivated one of ordinary skill in the art to use the methods of increasing energy reserves, sustaining energy production and modulating energy flow in a subject suffering from a skin disorder, as claimed by Appellant. Therefore, Appellant respectfully submits that claims 68-70, 75-80, 84 and 85 are patentable over the '688 patent in view of the '731 patent and the '063 application.

B. Rejection of Claims 68-70, 75-85 and 88 Under 35 U.S.C. §103(a)

The Examiner rejects claims 68-70, 75-85 and 88 under 35 U.S.C. §103(a) as being unpatentable over Le Fur *et al.* (U.S. Patent No. 5,256,649; hereinafter "the '649 patent;" Appendix E) in view of Carniglia (U.S. Patent No. 4,871,718; hereinafter "the '718 patent;" Appendix F) and the '063 application or Kaddurah-Daouk *et al.* (U.S. Patent No. 5,321,030; hereinafter "the '030 patent;" Appendix G).

Claims 68-70, 75-80, 84 and 85 are described immediately above in section A. Claim 81, which depends on claim 80, is directed to a vitamin selected from the group consisting of E, C, B5, B6, and B9. Claim 82, which depends on any one of claims 68-70 is directed to the co-administration of a sunscreen or a sunblock. Claim 83, which depends on claim 82, is directed to a sunscreen or sunblock with is zinc oxide or titanium dioxide. Claim 88, which depends on any one of claims 68-70, is directed to a skin disorder that is skin wrinkles.

The Examiner takes the position that "it would have been obvious to one of ordinary skill in the art to substitute [an] ATP generating systems with creatine (or its salts) when Le Fur [the '649 patent] is taken in view of Carniglia [the '718 patent] and Kaddurah-Daouk *et al.* [the '030 patent or the '063 application] because both Carniglia and Kaddurah-Daouk *et al.*'s patent together remedy the deficiencies of Le Fur's."

The Examiner further asserts that

> the modification of cellular energy level via increasing energy reserve, sustaining energy production and modulating energy flow is [an] inherently possessed feature where the intracellular energy metabolism in [the] skin cell is modified by creatine supplement because creatine is also found in [the] skin cell as well as brain, heart and muscle cells...

The '649 patent is directed to a cosmetic composition for combating aging of the skin, by administering an ademetionine (SAMe) generating system. Specifically, the composition disclosed in the '649 patent requires betaine, ATP or an ATP generating system, a magnesium salt, and a potassium salt and that ***the combination of the betaine and the ATP generating system*** are important to generate ademetionine *in situ* to treat the skin. Moreover, the methods taught by the '649 patent are limited to methods of treating the skin using ***ademetionine*** or precursors thereof. The '649 patent does not teach or suggest any methods using an ***ATP generating system alone***, let alone ***methods of administering creatine*** to the skin of a subject who is suffering from a skin disorder associated with free-radicals, aging, sun radiation, stress or fatigue, as claimed by Applicant.

The '718 patent fails to overcome the deficiencies of the primary reference. Specifically, the '718 patent teaches compositions comprising amino acids (*e.g.*, metabolic precursors of ATP), metabolites (*e.g.*, inositol), electrolytes (*e.g.*, magnesium phosphate) and a pentose sugar (*e.g.*, d-ribose), which are useful for increasing ATP levels, physical performance levels and the rate of wound repair. Specifically, the '718 patent discloses that the rate of localized wound contraction produced by myofibroblasts is dependent on the amount of ATP available as an intracellular source. While the '718 patent discloses that ATP serves as an energy source for other wound repair processes, such as granulation of the wound by fibroblasts, gluconeogenesis, protein synthesis and epithelialization, the '718 patent fails to teach or suggest ***methods for increasing energy reserves, sustaining energy production or modulating energy flow in the skin by administering to a subject an effective amount of creatine or a salt thereof*** to a subject suffering from a skin disorder associated with free-radicals, aging, sun radiation, stress or fatigue. Accordingly, based on the teaching of the '718 patent, alone or in view of the

primary reference, the subject matter presently claimed by Appellant would not have been obvious to one of ordinary skill in the art.

The '063 application, alone or in combination with the '718 patent, fails to overcome the deficiencies of the primary reference. The '063 application, as described immediately above in section A, teaches methods of treating diseases of the nervous system (*e.g.*, Alzheimer's disease, Parkinson's disease, Huntington's disease and the like) in a subject by administering to the subject an amount of one or more compounds (*e.g.*, creatine, creatine phosphate and analogs thereof) which modulate one or more of the structural or functional components of the creatine kinase/phosphocreatine system sufficient to prevent, reduce or ameliorate the symptoms of the disease. As described above, although the '063 application discloses that the function of the ***creatine kinase/phosphocreatine system*** includes the regeneration of energy in cells and that modulation the activity of creatine kinase would modulate energy flow and affect cell function, there is no teaching or suggestion of methods for increasing energy reserves, sustaining energy production and ***modulating energy flow in the skin*** by administering to a subject an ***effective amount of creatine or a salt thereof*** to a subject suffering from a skin disorder associated with free-radicals, aging, sun radiation, stress or fatigue. Accordingly, based on the teaching of the '063 application, alone or in combination with the '649 patent or the '718 patent, the subject matter presently claimed by Appellant would not have been obvious to one of ordinary skill in the art.

The '030 patent, alone or in combination with the '718 patent, also fails to provide any teaching or suggestion which would have led one of ordinary skill in the art to the claimed invention. The '030 patent teaches the use of ***creatine analogs*** (*e.g.*, cyclocreatine) as anti-viral agents. Specifically, the '030 patent teaches that creatine analogs can be used for treatment of a variety of infections caused by DNA viruses (*e.g.*, adenoviruses, herpes simplex virus, cytomegalovirus, etc...) and RNA viruses (*e.g.*, influenza). The '030 further teaches that because creatine kinase plays an important role in controlling the flow of energy inside a cell, the induction of creatine kinase by the virus might facilitate the generation and release of cellular energy reserves required for stages of viron replication and production. Accordingly, the inhibition of creatine kinase or interference with the normal activity of creatine kinase may block the production of a

progeny virus. Therefore, similar to the '731 patent described in section A immediately above, the '030 patent teaches ***away*** from the use of creatine or a salt thereof for the treatment of viruses because ***creatine is a substrate for creatine kinase.*** Thus, the administration of creatine or a salt thereof would be expected to increase the rate of the reaction of creatine kinase, thus increasing the energy reserves for use by the virus. Accordingly, the '030 patent, alone or in combination with the '718 patent or the '649 patent, would not have provided motivation for the skilled artisan to conceive of the present invention.

In sum, none of the cited references, either alone or in combination, provide any teaching or suggestion which would have motivated one of ordinary skill in the art to use the methods of increasing energy reserves, sustaining energy production and modulating energy flow in a subject suffering from a skin disorder, as claimed by Appellant. Therefore, Appellant respectfully submits that claims 68-70, 75-85 and 88 are patentable over the '649 patent in view of the '718 patent and the '063 application or the '030 patent.

VIII. CLAIMS

A copy of the claims involved in the present appeal is attached hereto as Appendix A.

IX. EVIDENCE

No evidence pursuant to §§ 1.130, 1.131, or 1.132 is being submitted. However, evidence entered by or relied upon by the examiner is being submitted, as indicated immediately below and in the attached Appendices B-G.

Appendix B is a copy of U.S. Patent No. 5,702,688 (the '688 patent) to Yu *et al.*, originally cited by Appellant in an Information Disclosure Statement received by the U.S. Patent and Trademark Office on October 20, 2004.

Appendix C is a copy of U.S. Patent No. 5,324,731 (the '731 patent) to Kaddurah-Daouk *et al.* originally cited by Appellant in an Information Disclosure Statement received by the U.S. Patent and Trademark Office on April 21, 2003.

Appendix D is a copy of International Application Publication No. WO 96/14063 to Kaddurah-Daouk *et al.* originally cited by Appellant in an Information Disclosure Statement received by the U.S. Patent and Trademark Office on April 21, 2003.

Appendix E is a copy of U.S. Patent No. 5,256,649 (the '649 patent) to Le Fur *et al.* originally cited in the Office Action mailed from the U.S. Patent and Trademark Office on November 26, 2005.

Appendix F is a copy of U.S. Patent No. 4,871,718 (the '718 patent) to Carniglia originally cited in the Office Action mailed from the U.S. Patent and Trademark Office on January 1, 2005.

Appendix G is a copy of U.S. Patent No. 5,321,030 (the '030 patent) to Kaddurah-Daouk *et al.* originally cited by Appellant in an Information Disclosure Statement received by the U.S. Patent and Trademark Office on April 21, 2003.

X. RELATED PROCEEDINGS

No related proceedings are referenced in II. above, or copies of decisions in related proceedings are not provided, hence no Appendix regarding related proceedings is included.

Dated: January 22, 2007

Respectfully submitted,

By _____

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Attorney/Agent For Appellant

APPENDIX A

Claims Involved in the Appeal of Application Serial No. 09/852,966

Claims 1- 67 **(Cancelled)**

68. **(Previously Presented)** A method for increasing energy reserves in the skin of a subject, comprising administering to said subject an effective amount of creatine or a salt thereof, such that the energy reserves in the skin of said subject is increased, wherein said subject is suffering from a skin disorder associated with free-radicals, aging, sun radiation, stress or fatigue.

69. **(Previously Presented)** A method for sustaining energy production in the skin of a subject, comprising administering to said subject an effective amount of creatine or a salt thereof, such that energy production the skin of said subject is sustained, wherein said subject is suffering from a skin disorder associated with free-radicals, aging, sun radiation, stress or fatigue.

70. **(Previously Presented)** A method for modulating energy flow in the skin of a subject, comprising administering to said subject an effective amount of creatine or a salt thereof, such that the energy flow in the skin of said subject is modulated, wherein said subject is suffering from a skin disorder associated with free-radicals, aging, sun radiation, stress or fatigue.

71. **(Cancelled)**

72. **(Previously Presented)** The method of claim 68, 69, or 70, wherein said creatine salt is creatine monohydrate.

73. **(Previously Presented)** The method of claim 68, 69, or 70, wherein said creatine salt is creatine citrate.

74. **(Cancelled)**

75. **(Previously Presented)** The method of any one of claims 68-70, further comprising co-administering to said subject an effective amount of a skin preserving agent.

76. **(Previously Presented)** The method of claim 75, wherein said skin preserving agent is an antioxidant.

77. **(Previously Presented)** The method of claim 76, wherein said antioxidant is CoQ_{10} or vitamin E.

78. **(Previously Presented)** The method of claim 76, wherein the skin preserving agent is an energy-enhancing agent.

79. **(Previously Presented)** The method of claim 78, wherein said energy enhancing agent is selected from the group consisting of ATP, nicotinamide and pyruvate.

80. **(Previously Presented)** The method of claim 75, wherein said skin preserving agent is a vitamin or a vitamin precursor.

81. **(Previously Presented)** The method of claim 80, wherein said vitamin is selected from the group consisting of E, C, B5, B6, and B9.

82. **(Previously Presented)** The method of any one of claims 68-70, further comprising the coadministration of a sunscreen or sunblock.

83. **(Previously Presented)** The method of claim 82, wherein said sunscreen or sunblock is zinc oxide or titanium dioxide.

84. **(Previously Presented)** The method of any one of claims 68-70, further comprising the coadministration of a pharmaceutical carrier suitable for topical administration.

85. **(Previously Presented)** The method of any one of claims 68-70, wherein said subject is a human.

86. **(Cancelled)**

87. **(Cancelled)**

88. **(Previously Presented)** The method of claim 68, 69, or 70, wherein said skin disorder is skin wrinkles.